

REMARKS

Claims 1-16 and 52 are pending in this application. Claims 1, 9, 11, 13 and 52 have been amended. Accordingly, Claims 1-16 and 52 will remain pending in the Application upon entry of the Claim Amendments presented herein.

Claims 1, 9, 11, 13, and 52 have been amended to recite that the small molecule is a non-proteinaceous small molecule. Support for this amendment can be found throughout the Specification as originally filed; in particular, at least, for example, at Page 6, Line 4. No new matter has been added.

Amendment of the Claims is not to be construed as acquiescence to any objections/rejections set forth in the pending Office Action, or any previous Office Action, and was done solely to expedite prosecution of the Application. Applicants respectfully reserve the right to pursue any non-elected, canceled, or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

The undersigned respectfully thank the Examiner for his suggestion of an interview with the Applicants. Applicants look forward to conducting an interview with the Examiner before the next office Action on the merits issued. Applicants are in the process of arranging a proposed time and look forward to having that interview in due course. In the meantime, Applicants respectfully request reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, as Applicants submit that the Application is in condition for allowance.

Rejections under 35 U.S.C. § 103(a)

Claims 1-16, and 52 are rejected under 35 U.S.C. 103 (a), as unpatentable over the combination of PCT International Patent Publication No. WO 00/70334A1 to Lee ("Lee") in

view of United States Published Patent Application No. US 2005/0153346 to Schneider ("Schneider"). Applicants respectfully disagree and traverse the rejection.

To properly determine a *prima facie* case of obviousness, the Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." M.P.E.P. § 2142. This is important as "impermissible hindsight must be avoided and the legal conclusion must be gleaned from the prior art." *Id.*

Three criteria may be helpful in determining whether claimed subject matter is obvious under 103(a): first, if there is some suggestion or motivation to modify or combine the cited references; second, if there is a reasonable expectation of success; and third, if the prior art references teach or suggest all the claim limitations. *KSR Int'l Co. v. Teleflex, Inc.* No 04-1350 (U.S. Apr. 30, 2007); M.P.E.P. 2143. With regard to the first criterion, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.3d 690 (Fed. Cir. 1990). "Knowledge in the prior art of every element of a patent claim ... is not of itself sufficient to render claim obvious." *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1333-34 (Fed. Cir. 2002)]. The issue is whether there is an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *KSR Int'l Co. v. Teleflex, Inc.*

Claim 1 recites a method for analysis of a non-proteinaceous small molecules comprising contacting a sample; said sample containing at least one non-proteinaceous small molecule with a surfactant.. As discussed in prior responses, Lee is related to the analysis of large molecules, *specifically proteins or peptides*. The Examiner alleges that Lee, in teaching the potential use of MALDI, shows that is desirable to use the elected surfactant to improve the analysis of "digests" and equates the presumed "digests" of Lee with non-proteinaceous small molecules. As all of the large molecules of Lee are *proteinaceous, i.e. proteins or peptides*, the MALDI digests of Lee would also be *proteinaceous*. That is to say, the energy adsorbed by the sample in a MALDI analysis of a peptide or protein would result in the

creation of an ionized peptide or protein. The Examiner has not shown any suggestion, in Lee or in the art, that would indicate that not a non-proteinaceous small molecule would result from the MALDI analysis of a protein or a peptide. As such, nothing in Lee teaches or suggests the analysis of non-proteinaceous small molecules. Moreover, there is no teaching or suggestion in Lee of the equivalence of proteinaceous and non-proteinaceous molecules, whether large or small, such that all molecules of whatever type would be amenable to the same types of analysis. Indeed, the Examiner has acknowledged as much on Page 5, last paragraph, where he states that "... it is understood that different classes of compounds lend themselves to different types of analysis."

Schneider does nothing to rectify the deficiencies of Lee. Schneider merely describes the use of MALDI for the analysis of different sized molecules. Indeed, a careful reading of Schneider would lead one of ordinary skill in the art away from the Examiner's assertion that MALDI analysis would digest large molecules into small molecules as Schneider states that MALDI is one of "the best able to *ionize large*, low volatility *molecular species*." (See, Paragraph 125, emphasis added). As such, even if one of ordinary skill were to look to Schneider for the teaching that MALDI can be used for non-proteinaceous small molecular species, the same artisan would have been taught that *proteinaceous large molecules are ionized* by MALDI and not digested into non-proteinaceous small molecular species.

Thus, one of ordinary skill would have had no motivation to combine the MALDI teachings of Schneider with large molecule analysis of Lee, let alone modify those teachings to arrive at the small molecule analysis method of the claimed invention.

Even if one of ordinary skill in the art were motivated to combine the references, Applicants respectfully submit that he would have lacked the necessary expectation of success in utilizing a surfactant as described by Lee for the analysis of one or more non-proteinaceous small molecules contained within a sample. At best, one of ordinary skill in the art may have expected the surfactant to assist in the analysis of proteins or peptides found in the sample, as surfactants have historically been used only for the analysis of similar large molecules due to their binding characteristics. (See background section of Application.)

Accordingly, Applicants respectfully request reconsideration and withdrawal of all rejections under 35 U.S.C. § 103 of claims 1-16 and 52.

CONCLUSION

In view of the remarks made herein, Applicant submits that the application is in condition for allowance, and respectfully request favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. If a telephone conference with Applicant's representative would be helpful in expediting prosecution of the application, Applicants invite the Examiner to contact the undersigned at the telephone number indicated below.

Applicant believes that no additional fees, other than the fee for the RCE and the two -month extension of time, are required in connection with this paper. Nevertheless, Applicants authorize the Director to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to Deposit Account No. 04-1105, under Order No. 60008US(49991).

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Respectfully Submitted,

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